

Message

From: Bohnenblust, Eric [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0331C49AEB404367AD226F6BD10D795D-BOHNENBLUST]
Sent: 3/18/2020 5:23:17 PM
To: Wakefield, Benjamin J. [wakefield.benjamin@epa.gov]; Kaczmarek, Chris [Kaczmarek.Chris@epa.gov]
CC: Milewski, Elizabeth [Milewski.Elizabeth@epa.gov]; Huskey, Angela [Huskey.Angela@epa.gov]; Mendelsohn, Mike [Mendelsohn.Mike@epa.gov]
Subject: FW: Human Studies related comments on Oxitec OX5034 EUP
Attachments: OX5034 informed consent and ethical concern comments 03 03 2020 MA edits.docx

Ben,

Just as an FYI in response to one of your questions. Here is the status of the human studies related comments. Angela was cc'd on Michelle's response but I haven't had a chance to look at the response or engage Angela on this yet.

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From: Arling, Michelle <Arling.Michelle@epa.gov>
Sent: Tuesday, March 17, 2020 11:42 AM
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Cc: Milewski, Elizabeth <Milewski.Elizabeth@epa.gov>; Mendelsohn, Mike <Mendelsohn.Mike@epa.gov>; Huskey, Angela <Huskey.Angela@epa.gov>
Subject: RE: Human Studies related comments on Oxitec OX5034 EUP

Hi all,

Here are my edits to this section of the response to comments. I updated the language from the human studies rule (amended last year) and then added more specifics to the discussion. There are a few comment bubbles for you to address. Please let me know if you have any questions.

Thanks,
Michelle

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From: Bohnenblust, Eric <Bohnenblust.Eric@epa.gov>
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To: Arling, Michelle <Arling.Michelle@epa.gov>
Cc: Milewski, Elizabeth <Milewski.Elizabeth@epa.gov>; Mendelsohn, Mike <Mendelsohn.Mike@epa.gov>; Huskey,

Angela <Huskey.Angela@epa.gov>

Subject: Human Studies related comments on Oxitec OX5034 EUP

Michelle,

Attached is a document summarizing all of the human studies related public comments on the OX5034 EUP application. We pulled the draft response you provided in response to comments on the previous EUP. I added a comment in the document, I'm not sure about the relevance of the one sentence and the highlighted sentences are where you previously asked for us to fill in info. Please look through and modify the response as necessary in light of the comments. I've cc'd Angela Huskey, so OGC know where this stands.

We are looking for turnaround in about 2 weeks, so ideally no later than March 18. Let me know if you need any more info, or if something comes up and this isn't turnaround time isn't possible.

Thanks for your help.

Eric Bohnenblust, Ph.D

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